TRANSACTIONS GRANTED EARLY TERMINATION BETWEEN: 110695 AND 111795—Continued

Name of acquiring person, name of acquired person, name of acquired entity	PMN No.	Date termi- nated
Cox Enterprises, Inc., James M. Moran, Greater Auction Group, Inc	96–0301 96–0306 96–0311	11/17/95 11/17/95 11/17/95
ship		11/17/95

FOR FURTHER INFORMATION CONTACT:

Sandra M. Peay or Renee A. Horton, Contact Representatives, Federal Trade Commission, Premerger Notification Office, Bureau of Competition, Room 303, Washington, DC 20580, (202) 326– 3100.

By Direction of the Commission. Donald S. Clark,

Secretary.

[FR Doc. 95–30083 Filed 12–8–95; 8:45 am] BILLING CODE 6750–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Citizens Advisory Committee on Public Health Service Activities and Research at Department of Energy (DOE) Sites: Idaho National Engineering Laboratory Health Effects Subcommittee and Idaho National Engineering Laboratory Worker Epidemiologic Study Public Meetings: Date Change

Federal Register Citation of Previous Announcement: 60 FR 58629—dated November 28, 1995.

SUMMARY: Notice is given that the meeting date for the Idaho National Engineering Laboratory Worker Epidemiologic Study Public Meeting (INEL), of the Centers for Disease Control and Prevention (CDC) has changed. The meeting time, place, status, purpose, and matters to be discussed announced in the original notice remain unchanged.

ORIGINAL DATE: December 13, 1995.

NEW DATE: December 12, 1995.

CONTACT PERSONS FOR MORE

INFORMATION: Arthur J. Robinson, Jr., or Nadine Dickerson, Radiation Studies Branch, Division of Environmental Hazards and Health Effects, NCEH, CDC, 4770 Buford Highway, NE., (F–35), Atlanta, Georgia 30341–3724, telephone 770/488–7040, FAX 770/488–7044. Dated: December 6, 1995.

Nancy C. Hirsch,

Acting Director, Management Analysis and Services Office Centers for Disease Control and Prevention (CDC).

[FR Doc. 95–30168 Filed 12–7–95; 11:22 am] BILLING CODE 4163–18–M

Health Care Financing Administration

[ORD-081-N]

New and Pending Demonstration Project Proposals Submitted Pursuant to Section 1115(a) of the Social Security Act: August and September 1995

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice.

SUMMARY: This notice lists new proposals for Medicaid demonstration projects submitted to the Department of Health and Human Services during the months of August and September 1995 under the authority of section 1115 of the Social Security Act. This notice also lists proposals that were approved, disapproved, pending, or withdrawn during this time period. (This notice can be accessed on the Internet at HTTP://WWW.SSA.GOV/HCFA/HCFAHP2.HTML.)

comments: We will accept written comments on these proposals. We will, if feasible, acknowledge receipt of all comments, but we will not provide written responses to comments. We will, however, neither approve nor disapprove any new proposal for at least 30 days after the date of this notice to allow time to receive and consider comments. Direct comments as indicated below.

ADDRESSES: Mail correspondence to: Susan Anderson, Office of Research and Demonstrations, Health Care Financing Administration, Mail Stop C3–11–07, 7500 Security Boulevard, Baltimore, MD 21244–1850.

FOR FURTHER INFORMATION CONTACT: Susan Anderson, (410) 786–3996.

SUPPLEMENTARY INFORMATION:

I. Background

Under section 1115 of the Social Security Act (the Act), the Department of Health and Human Services (HHS) may consider and approve research and demonstration proposals with a broad range of policy objectives. These demonstrations can lead to improvements in achieving the purposes of the Act.

In exercising her discretionary authority, the Secretary has developed a number of policies and procedures for reviewing proposals. On September 27, 1994, we published a notice in the Federal Register (59 FR 49249) that specified (1) The principles that we ordinarily will consider when approving or disapproving demonstration projects under the authority in section 1115(a) of the Act; (2) the procedures we expect States to use in involving the public in the development of proposed demonstration projects under section 1115; and (3) the procedures we ordinarily will follow in reviewing demonstration proposals. We are committed to a thorough and expeditious review of State requests to conduct such demonstrations.

As part of our procedures, we publish a notice in the Federal Register with a monthly listing of all new submissions, pending proposals, approvals, disapprovals, and withdrawn proposals. Proposals submitted in response to a grant solicitation or other competitive process are reported as received during the month that such grant or bid is awarded, so as to prevent interference with the awards process.

II. Listing of New, Pending, Approved, and Withdrawn Proposals for the Months of August and September 1995

A. Comprehensive Health Reform Programs

1. New Proposals

No new proposals were received during the month of August.

The following comprehensive health reform proposals were received during the month of September.

Demonstration Title/State: The Georgia Behavioral Health Plan— Georgia.

Description: Georgia proposes to provide behavioral health services under a managed care system through the section 1115 demonstration. The plan would be implemented by regional boards that would contract with third party administrators to develop a network of behavioral health providers. The currently eligible Medicaid population would be enrolled in the program and would have access to a full range of behavioral health services. Once the program realizes savings, the State proposes to expand coverage to individuals who become newly eligible.

Date Received: September 1, 1995. State Contact: Margaret Taylor, Coordinator for Strategic Planning, Department of Medical Assistance, 1 Peachtree Street NW., Suite 27–100, Atlanta, GA 30303–3159, (404) 657–2012.

Federal Project Officer: Nancy Goetschius, Health Care Financing Administration Office of Research and Demonstrations, Mail Stop C3–18–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Demonstration Title/State: State of Texas Access Reform (STAR)—Texas.

Description: Texas is proposing a section 1115 demonstration that will restructure the Medicaid program using competitive managed care principles. A focal point of the proposal is to utilize local governmental entities (referred to as Intergovernmental Initiatives (IGIs)) and to make the IGI responsible for designing and administering a managed care system in its region. Approximately 876,636 new beneficiaries would be served during the 5-year demonstration in addition to the current Medicaid population. Texas proposes to implement the program in June 1996.

Date Received: September 6, 1995. State Contract: Cathy Rossberg, State Medicaid Office, P.O. Box 13247, Austin, TX 78711, (512) 502–3224.

Federal Project Officer: Alisa Adamo, Health Care Financing Administration, Office of Research and Demonstrations, Mail Stop C3–18–26, 7500 Security Boulevard, Baltimore, MD 21244–1850.

2. Pending Proposals

Demonstration Title/State: Better Access for You (BAY) Health Plan Demonstration—Alabama.

Description: Alabama proposes to create a mandatory managed care delivery system in Mobile County for non-institutionalized Medicaid beneficiaries and an expansion population of low-income women and children. The network, called the Bay Health Network, would be administered by the PrimeHealth Organization, which is owned by the University of South Alabama Foundation. The State also proposes to expand family planning benefits for pregnant women whose income is less than 133 percent of the Federal poverty level.

Date Received: July 10, 1995. State Contact: Vicki Huff, Director, Managed Care Division, Alabama Medicaid Agency, PO. Box 5624, Montgomery, AL 36103–5624, (334) 242–5011.

Federal Project Officer: Maria Boulmetis, Health Care Financing Administration, Office of Research and Demonstrations, Mail Stop C3–18–26, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Demonstration Title/State: Arizona Health Care Cost Containment System (AHCCCS)—Arizona.

Description: Arizona proposes to expand eligibility under its current section 1115 AHCCCS program to individuals with incomes up to 100 percent of the Federal poverty level.

Date Received: March 17, 1995. State Contact: Mabel Chen, M.D., Director, Arizona Health Care Cost Containment System, 801 East Jefferson, Phoenix, AZ 85034, (602) 271–4422.

Federal Project Officer: Joan Peterson, Health Care Financing Administration, Office of Research and Demonstrations, Mail Stop C3–18–26, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Demonstration Title/State: MediPlan Plus—Illinois.

Description: Illinois seeks to develop a managed care delivery system using a series of networks, either local or statewide, to tailor its Medicaid delivery system to the needs of local urban neighborhoods or large rural areas.

Date Received: September 15, 1994. State Contact: Tom Toberman, Manager, Federal/State Monitoring, 201 South Grand Avenue East, Springfield, IL 62763, (217) 782–2570.

Federal Project Officer: Gina Clemons, Health Care Financing Administration, Office of Research and Demonstrations, Mail Stop C3–18–26, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Demonstration Title/State: Community Care of Kansas—Kansas.

Description: Kansas proposes to implement a "managed cooperation demonstration project" in four predominantly rural counties, and to assess the success of a non-competitive managed care model in rural areas. The demonstration would enroll persons currently eligible in the Aid to Families with Dependent Children (AFDC) and AFDC-related eligibility categories, and expand Medicaid eligibility to children

ages 5 and under with family incomes up to 200 percent of the Federal poverty level.

Date Received: March 23, 1995. State Contact: Karl Hockenbarger Kansas Department of Social and Rehabilitation Services, 915 Southwest Harrison Street, Topeka, KS 66612, (913) 296–4719.

Federal Project Officer: Jane Forman, Health Care Financing Administration, Office of Research and Demonstrations, Mail Stop C3–21–04, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Demonstration Title/State: Kentucky Health Care Partnership—Kentucky.

Description: Kentucky proposes to enroll all non-institutional AFDC, AFDC-related, and aged, blind, and disabled Medicaid-eligible individuals in regional managed care networks operated by a sole-source contractor. The proposed start date of the demonstration is December 1, 1995.

Date Received: June 19, 1995. State Contact: Larry A. McCarthy, Director, Program Development and Budget, Department of Medicaid Services, 275 East Main Street, Frankfort, KY 40621, (406) 444–4540.

Federal Project Officer: Maria Boulmetis, Health Care Financing Administration, Office of Research and Demonstrations, Mail Stop C3–18–26, 7500 Security Boulevard, Baltimore, MD 21244–1850,

Demonstration Title/State: Louisiana Health Access—Louisiana.

Description: Louisiana proposes to implement a fully capitated statewide managed care program. A basic benefit package and a behavioral health and pharmacy wrap-around would be administered through the managed care plans. The State intends to expand Medicaid eligibility to persons with incomes up to 250 percent of the Federal poverty level; those with incomes above 133 percent of the Federal poverty level would pay all or a portion of premiums.

Date Received: January 3, 1995. State Contact: Carolyn Maggio, Executive Director, Bureau of Research and Development, Louisiana Department of Health and Hospitals, P.O. Box 2870, Baton Rouge, LA 70821– 2871, (504) 342–2964.

Federal Project Officer: Gina Clemons, Health Care Financing Administration, Office of Research and Demonstrations, Mail Stop C3–18–26, 7500 Security Boulevard, Baltimore, MD 21244–1850,

Demonstration Title/State: Missouri. Description: Missouri proposes to require Medicaid beneficiaries to enroll in managed care delivery systems, and extend Medicaid eligibility to persons with incomes below 200 percent of the

Federal poverty level. As part of the program, Missouri would create a fully capitated managed care pilot program to serve non-institutionalized persons with permanent disabilities on a voluntary basis.

Date Received: June 30, 1994. State Contact: Donna Checkett, Director, Division of Medical Services, Missouri Department of Social Services, P.O. Box 6500, Jefferson City, MO 65102–6500, (314) 751–6922.

Federal Project Officer: Nancy Goetschius, Health Care Financing Administration, Office of Research and Demonstrations, Mail Stop C3–18–26, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Demonstration Title/State: The Granite State Partnership for Access and Affordability in Health Care—New Hampshire.

Description: New Hampshire proposes to extend Medicaid eligibility to adults with incomes below the AFDC cash standard and to create a public insurance product for low-income workers. The State also seeks to implement a number of pilot initiatives to help redesign its health care delivery system.

Date Received: June 14, 1994. State Contact: Barry Bodell, New Hampshire Department of Health and Human Services, Office of the Commissioner, 6 Hazen Drive, Concord, NH 03301–6505, (603) 271–4332.

Federal Project Officer: Maria Boulmetis, Health Care Financing Administration, Office of Research and Demonstrations, Mail Stop C3–18–26, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Demonstration Title/State: The Partnership Plan—New York.

Description: New York proposes to move most of the currently eligible Medicaid population and Home Relief (General Assistance) populations from a primarily fee-for-service system to a managed care environment. The State also proposes to establish special needs plans to serve individuals with HIV/AIDS and certain children with mental illnesses. The proposed enrollment date for Home Relief and AFDC recipients is November 1, 1995, followed by a 1-year enrollment period for the supplemental security income (SSI) population beginning January 1, 1997.

Date Received: March 17, 1995. State Contact: Richard T. Cody, Deputy Commissioner, Division of Health and Long Term Care, 40 North Pearl Street, Albany, NY 12243, (518) 474–9132.

Federal Project Officer: Debbie Van Hoven, Health Care Financing Administration, Office of Research and Demonstrations, Mail Stop C3–18–26, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Demonstration Title/State: SoonerCare—Oklahoma.

Description: Oklahoma proposes to implement a 5-year statewide managed care demonstration using both fully and partially capitated delivery systems. The emphasis of the program is to address access problems in rural areas by encouraging the development of ruralbased managed care initiatives. The State will employ traditional fully capitated managed care delivery models for urban areas and will introduce a series of partial capitation models in the rural areas of the State. All currently eligible, non-institutionalized Medicaid beneficiaries will be enrolled during the first 2 years of the project.

Date Received: January 6, 1995.

State Contact: Dr. Garth Splinter, Oklahoma Health Care Authority, Lincoln Plaza, 4545 North Lincoln Blvd., Suite 124, Oklahoma City, OK 73105, (405) 530–3439.

Federal Project Officer: Helaine I. Fingold, Health Care Financing Administration, Office of Research and Demonstrations, Mail Stop C3–18–26, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Demonstration Title/State: Section 1115 Demonstration Waiver for Medicaid Expansion—Utah.

Description: Utah proposes to expand eligibility for Medicaid to all individuals with incomes up to 100 percent of the Federal poverty level (subject to limited cost sharing) and to enroll all Medicaid beneficiaries in managed care plans. The State also proposes to streamline eligibility and administrative processes and to develop a subsidized small employer health insurance plan.

Date Received: July 5, 1995.

State Contact: Michael Deily, Acting Division Director, Utah Department of Health, Division of Health Care Financing, 288 North 1460 West, P.O. Box 142901, Salt Lake City, UT 84114–2901, (801) 538–6406.

Federal Project Officer: David Walsh, Health Care Financing Administration, Office of Research and Demonstrations, Mail Stop C3–18–26, 7500 Security Boulevard, Baltimore, MD 21244–1850.

3. Approved Conceptual Proposals (Awards of Waivers Pending)

No conceptual proposals were approved during the months of August and September.

4. Approved Grant Proposals (Award of Waivers Pending)

No grant proposals were awarded during the months of August and September.

5. Approved Proposals

No proposals were approved during the months of August and September.

6. Disapproved Proposals

No comprehensive health reform proposals have been disapproved since January 1, 1993.

7. Withdrawn Proposals

No comprehensive health reform proposals were withdrawn during the months of August and September.

B. Other Section 1115 Demonstration Proposals

1. New Proposals

No new proposals were received during the month of August.

The following proposal was received during the month of September:

Demonstration/Title: Integrated Care and Financing Project Demonstration—Colorado.

Description: Colorado proposes to conduct an Integrated Care and Financing Project demonstration. Specifically, the Colorado Department of Health Care Policy and Financing proposes to add institutional and community-based long-term care services to a health maintenance organization (HMO) and make the HMO responsible for providing comprehensive medical and supportive services through one capitated rate. The project would include all Medicaid eligibility groups, including individuals with dual eligibility.

Date Received: September 28, 1995. State Contact: Dann Milne, Office of Long-Term Care System Development, State of Colorado Department of Health Care Policy and Financing, 1575 Sherman Street, Denver, CO 80203– 1714, (303) 866–5912.

Federal Contact: Melissa McNiff, Health Care Financing Administration, Office of Research and Demonstrations, Mail Stop C3–18–26, 7500 Security Boulevard, Baltimore, MD 21244–1850.

2. Pending Proposals.

Demonstration Title/State: Alternatives in Medicaid Home Care Demonstration—Colorado.

Description: Colorado proposes to conduct a pilot project that eliminates the restriction on provision of Medicaid home health services in locations other than the beneficiary's place of residence. The proposal would also permit nursing aides to perform functions that historically have been provided only by skilled nursing staff. Medicaid beneficiaries participating in the project will be adults (including both frail elderly clients and younger clients with disabilities) who can live independently and self-direct their own care. The project would provide for delegation of specific functions from nurses to certified nurses aides, pay nurses for shorter supervision and monitoring visits, and allow higher payments to aides performing delegated nursing tasks. Currently, home health agency nursing and nurse aide services are paid on a per visit basis. Each visit is approximately 2–4 hours in duration, and recipients must require skilled, hands-on care.

Date Received: June 3, 1995. State Contact: Dann Milne, Director, Department of Health Care Policy and Financing, 1575 Sherman Street, Denver, CO 80203–1714, (303) 866– 5912

Federal Project Officer: Phyllis Nagy, Health Care Financing Administration, Office of Research and Demonstrations, Mail Stop C3–21–06, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Demonstration Title/State: Georgia's Children's Benefit Plan—Georgia.

Description: Georgia submitted a section 1115 proposal entitled "Georgia Children's Benefit Plan" to provide preventive and primary care services to children aged 1 through 5 living in families with incomes between 133 percent and 185 percent of the Federal poverty level. The duration of the project is 5 years with proposed project dates of July 1, 1995 to June 30, 2000.

Date Received: December 12, 1994. State Contact: Jacquelyn Foster-Rice, Georgia Department of Medical Assistance, 2 Peachtree Street Northwest, Atlanta, GA 30303–3159, (404) 651–5785.

Federal Project Officer: Maria Boulmetis, Health Care Financing Administration, Office of Research and Demonstrations, Mail Stop C3–18–26, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Demonstration Title/State: High Cost User Initiative—Maryland.

Description: Maryland proposes to implement an integrated case management system for high-cost, high-risk Medicaid beneficiaries.

Date Received: July 8, 1994. State Contact: John Folkemer, Maryland Department of Health and Mental Hygiene, Office of Medical Assistance Policy, 201 West Preston Street, Baltimore, MD 21201, (410) 225– 5206. Federal Project Officer: William Clark, Health Care Financing Administration, Office of Research and Demonstrations, Mail Stop C3–21–06, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Demonstration Title/State: Family Planning Services Section 1115 Waiver Request—Michigan.

Description: Michigan seeks to extend Medicaid eligibility for family planning services to all women of childbearing age with incomes at or below 185 percent of the Federal poverty level, and to provide an additional benefit package consisting of home visits, outreach services to identify eligibility, and reinforced support for utilization of services. The duration of the project is 5 years.

Date Received: March 27, 1995. State Contact: Gerald Miller, Director, Department of Social Services, 235 South Grand Avenue, Lansing, MI 48909, (517) 335–5117.

Federal Project Officer: Suzanne Rotwein, Ph.D., Health Care Financing Administration, Office of Research and Demonstrations, Mail Stop C3–24–07, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Demonstration Title/State: Montana Mental Health Access Plan—Montana.

Description: Montana proposes to provide all mental health services for current Medicaid-eligible individuals through managed care and to expand Medicaid eligibility to persons with incomes up to 200 percent of the Federal poverty level. Newly eligible individuals would receive only mental health benefits, and would not be eligible for other health services under the demonstration. A single statewide contractor would provide the mental health services and also determine eligibility, perform inspections, and handle credentialing.

Date Received: June 16, 1995. State Contact: Nancy Ellery, State Medicaid Director, Department of Social and Rehabilitation Services, P.O. Box 4210, 111 North Sanders, Helena, MT 59604–4210, (406) 444–4540.

Federal Project Officer: Nancy Goetschius, Health Care Financing Administration, Office of Research and Demonstrations, Mail Stop C3–18–26, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Demonstration Title/State: Family Planning Proposal—New Mexico.

Description: New Mexico proposes to extend Medicaid eligibility for family planning services to all women of childbearing age with incomes at or below 185 percent of the Federal poverty level.

Date Received: November 1, 1994.

State Contact: Bruce Weydemeyer, Director, Division of Medical Assistance, P.O. Box 2348, Santa Fe, NM 87504–2348, (505) 827–3106.

Federal Project Officer: Suzanne Rotwein, Ph.D., Health Care Financing Administration, Office of Research and Demonstrations, Mail Stop C3–24–07, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Demonstration Title/State: CHOICES—Citizenship, Health, Opportunities, Interdependence, Choices and Supports—Rhode Island.

Description: Rhode Island proposes to consolidate all current State and Federal funding streams for adults with developmental disabilities under one program using managed care/managed competition.

Date Received: April 5, 1994. State Contact: Susan Babin, Department of Mental Health, Retardation, and Hospitals, Division of Developmental Disabilities, 600 New London Avenue, Cranston, RI 02920, (401) 464–3234.

Federal Project Officer: Melissa McNiff, Health Care Financing Administration, Office of Research and Demonstrations, Mail Stop C3–21–06, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Demonstration Title/State: Family Planning Services Eligibility Requirements Waiver—South Carolina.

Description: South Carolina proposes to extend Medicaid coverage for family planning services for 22 additional months to postpartum women with monthly incomes under 185 percent of the Federal poverty level. The objectives of the demonstration are to increase the number of reproductive age women receiving either Title XIX or Title X funded family planning services following the completion of a pregnancy, increase the period between pregnancies among mothers eligible for maternity services under the expanded eligibility provisions of Medicaid, and estimate the overall savings in Medicaid spending attributable to providing family planning services to women for 2 years postpartum. The duration of the proposed project would be 5 years.

Date Received: May 4, 1995. State Contact: Eugene A. Laurent, Executive Director, State Health and Human Services Finance Commission, P.O. Box 8206, Columbia, SC 29202– 8206, (803) 253–6100.

Federal Project Officer: Suzanne Rotwein, Ph.D., Health Care Financing Administration, Office of Research and Demonstrations, Mail Stop C3–24–07, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Demonstration Title/State: Wisconsin.

Description: Wisconsin proposes to limit the amount of exempt funds that may be set aside as burial and related expenses for SSI-related Medicaid beneficiaries.

Date Received: March 9, 1994. State Contact: Jean Sheil, Division of Economic Support, Wisconsin Department of Health and Social Services, 1 West Wilson Street, Room 650, P.O. Box 7850, Madison, WI 53707, (608) 266–0613.

Federal Project Officer: J. Donald Sherwood, Health Care Financing Administration, Office of Research and Demonstrations, Mail Stop C3–16–26, 7500 Security Boulevard, Baltimore, MD 21244–1850.

3. Approved Conceptual Proposals (Award of Waivers Pending)

No conceptual proposals were awarded during the months of August and September.

4. Approved Proposals

No proposals were approved during the months of August and September.

5. Disapproved Proposals

No proposals were disapproved during the months of August and September.

6. Withdrawn Proposals

No proposals were withdrawn during the months of August and September.

IV. Requests for Copies of a Proposal

Requests for copies of a specific Medicaid proposal should be made to the State contact listed for the specific proposal. If further help or information is needed, inquiries should be directed to HCFA at the address above.

(Catalog of Federal Domestic Assistance Program, No. 93.779; Health Financing Research, Demonstrations, and Experiments)

Dated: November 30, 1995.

Bruce C. Vladeck,

Administrator, Health Care Financing Administration.

[FR Doc. 95–30066 Filed 12–8–95; 8:45 am] BILLING CODE 4120–01–P

National Institutes of Health

National Institute of Allergy and Infectious Diseases: Licensing Opportunity and/or Opportunity for a Cooperative Research and Development Agreement (CRADA) for the Development of Influenza A PB2 Gene Technology

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: The National Institutes of Health is seeking licensees and/or CRADA Collaborators for the joint research, development, evaluation, and commercialization of its influenza A polymerase basic 2 (PB2) patent portfolio. The inventions claimed in U.S. Patent Application Serial No. 08/ 123,933 ("Method for Generating Influenza A Viruses Bearing Attenuating Mutations in Internal Protein Genes," filed September 20, 1993), and its related patent applications, are available for either co-exclusive or non-exclusive licensing (in accordance with 35 U.S.C. 207 and 37 CFR Part 404) and/or further development under one or more CRADAs for important clinical and research applications described below in the Supplementary Information section.

DATES: License applications must be received on or before March 11, 1996. CRADA proposals should be received on or before April 11, 1996 for priority consideration. However, CRADA proposals submitted thereafter will be considered until a suitable CRADA Collaborator is selected.

ADDRESSES: CRADA proposals and questions about this opportunity should be addressed to: Claire T. Driscoll, Technology Transfer Manager, National Institute of Allergy and Infectious Diseases, National Institutes of Health, Building 31, Room 3B62, 9000 Rockville Pike, Bethesda, MD 20892; Telephone: 301/496–2644; Fax: 301/402–7123; Email: cd68y@nih.gov.

Licensing proposals and questions about this opportunity should be addressed to: Cindy K. Fuchs, J.D., Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; Telephone: 301/496–7735 ext. 232; Fax: 301/402–0220; E-mail: Cindy_Fuchs@nih.gov.

Information on the patent applications and pertinent information not yet publicly disclosed can be obtained under a Confidential Disclosure Agreement. Respondees interested in licensing the invention(s) will be required to submit an Application for License to Public Health Service Inventions. Respondees interested in submitting a CRADA proposal should be aware that it may be necessary to secure a license to the above patent rights in order to commercialize products arising from a CRADA agreement.

SUPPLEMENTARY INFORMATION: This invention involves the use of modern molecular virologic techniques to introduce temperature sensitive (ts)

attentuating mutations into a complementary DNA (cDNA) copy of the influenza A polymerase basic 2 (PB2) protein gene and to recover viruses bearing the mutant PB2 gene. Viral RNA (vRNA) transcribed in vitro from the PB2 DNA is transfected into avian kidney cells in the presence of an influenza A helper virus. The PB2 gene of the helper virus, which restricts its replication in mammalian cells, is substituted by the transfected mutant PB2 gene, which is known to function efficiently in mammalian cells. Using this system it has been possible to introduce three attenuating temperature sensitive mutations into the PB2 gene and to recover an infectious virus bearing this triple mutant gene. The virus bearing this mutant gene was highly attenuated in animals, was stable genetically even after prolonged replication in immunosuppressed rodents, and induced resistance to challenge with wild type influenza A virus. This gene can now be transferred from a donor virus to new epidemic or pandemic variants of influenza A virus as they appear in nature. The end result is a live attenuated reassortant influenza A virus vaccine that not only contains an attenuating PB2 gene from the attenuated donor but also the protective antigens, i.e., the hemagglutinin and neuraminidase glycoproteins, from the newly emerged wild type virus. Such a reassortant virus can serve as a protective vaccine, when administered into the respiratory tract of a vaccine, against disease caused by the epidemic influenza A viruses.

To speed the research, development, and commercialization of these agents, the NIH is seeking one or more license agreements and/or CRADAs with pharmaceutical or biotechnology companies in accordance with the regulations governing the transfer of Government-developed agents. Proposals relating to any biomedical area will be considered.

The CRADA aims will include the rapid publication of research results consistent with protection of proprietary information and patentable inventions as well as the timely exploitation of commercial opportunities. The CRADA Collaborator will enjoy the benefits of first negotiation for licensing Government rights to any inventions arising under the agreement and will advance funds payable upon signing the CRADA to help defray Government expenses for patenting such inventions and other CRADA-related costs.

The role of the National Institute of Allergy and Infectious Diseases will be as follows: